(RADV) Appeals and Health Insurance Exchange Outreach Training Sessions; *Use:* CMS recognizes that the success of accurately identifying risk-adjustment payments and payment errors is dependent upon the data submitted by Medicare Advantage Organizations (MAOs), and is strongly committed to providing appropriate education and technical outreach to MAOs and third-party administrators (TPAs). In addition, CMS is strongly committed to providing appropriate education and technical outreach to States, issuers, self-insured group health plans and TPAs participating in the Marketplace and/or market stabilization programs mandated by the Affordable Care Act (ACA).

CMS will strengthen outreach and engagement with MAOs and stakeholders in the Marketplace through satisfaction surveys following contract-level (CON) RADV audit and Health Insurance Exchange training events. The survey results will help to determine stakeholders' level of satisfaction with trainings, identify any issues with training and technical assistance delivery, clarify stakeholders' needs and preferences, and define best practices for training and technical assistance. *Form Number:* CMS–10764 (OMB control number: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Private Sector; *Number of Respondents:* 4,270; *Total Annual Responses:* 4,270; *Total Annual Hours:* 1,068. (For questions regarding this collection contact Melissa Barkai at 410–786–4305.)

Dated: May 17, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–10680 Filed 5–19–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0226]

Determination That AVACLYR (Acyclovir Ophthalmic Ointment), 3 Percent, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that AVACLYR (acyclovir ophthalmic ointment), 3 percent, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for acyclovir ophthalmic ointment, 3 percent, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nisha Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–4455, *Nisha.Shah@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

AVACLYR (acyclovir ophthalmic ointment), 3 percent, is the subject of NDA 202408, held by Fera Pharmaceuticals, LLC, and initially approved on March 29, 2019. AVACLYR is indicated for the treatment of acute herpetic keratitis (dendritic ulcers) in patients with herpes simplex (HSV–1 and HSV–2) virus.

In a letter dated August 21, 2019, Fera Pharmaceuticals, LLC notified FDA that AVACLYR (acyclovir ophthalmic ointment), 3 percent, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Cumulus Pharmaceutical LLC submitted a citizen petition dated February 23, 2021, (Docket No. FDA–2021–P–0226), under 21 CFR 10.30, requesting that the Agency determine whether AVACLYR (acyclovir ophthalmic ointment), 3 percent, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that AVACLYR (acyclovir ophthalmic ointment), 3 percent, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that AVACLYR (acyclovir ophthalmic ointment), 3 percent, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of AVACLYR (acyclovir ophthalmic ointment), 3 percent, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list AVACLYR (acyclovir ophthalmic ointment), 3 percent, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. Any ANDAs referencing AVACLYR (acyclovir ophthalmic ointment), 3 percent, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10593 Filed 5–19–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0166]

International Council for Harmonisation Q12: Implementation Considerations for Food and Drug Administration-Regulated Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''ICH Q12: Implementation Considerations for FDA-Regulated Products.'' The International Council for Harmonisation (ICH) guidance for industry entitled ''Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management'' and its Annexes (ICH Q12, May 2021) provide a framework to facilitate the management of postapproval chemistry, manufacturing, and controls (CMC) changes in a more predictable and efficient manner. ICH Q12 includes regulatory tools and enablers with associated guiding principles that should enhance industry's ability to manage postapproval changes and increase transparency between industry and regulatory authorities, supporting innovation and continual improvement. This guidance complements ICH Q12 by clarifying how its tools and enablers can be implemented within the U.S. regulatory system. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by July 19, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0166 for ''ICH Q12: Implementation Considerations for FDA-Regulated Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or Office of Policy, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ashley Boam, CDER, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4192, Silver Spring, MD 20993–0002, 301–796–6341; Stephen Ripley, CBER, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Andrew Yeatts, CDRH, Food and Drug Administration, 10903 New Hampshire